

## **REMARKS**

In the Final Action dated April 19, 2007, Claims 1-2, 7-10, 25, 28-30 and 36-52 are pending and under consideration. The Examiner states that Claims 37 and 45 are allowable. Claims 1, 2, 7-10, 25, 28-30, 36, 38-42 and 47-51 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. Claims 1, 2, 7-10, 25, 28-30, 36, 38-42 and 47-51 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 38-42 and 48-51 are also rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. Claims 43, 44, 46 and 52 are objected to as dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This response addresses each of the Examiner's objections and rejections.

Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

Claims 1, 2, 7-10, 25, 28-30, 36, 38-42 and 47-51 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. The Examiner acknowledges that the present application is enabling for an isolated nucleic acid molecule encoding a polypeptide comprising the entire extracellular domain (ECD) of SEQ ID NO: 4. However, the Examiner alleges that the present application does not provide enablement for an isolated nucleic acid encoding a derivative of SEQ ID NO: 4 that does not comprise the entire ECD of SEQ ID NO: 4.

The Examiner contends that the scope of the claims encompasses variants with multiple mutations within the ECD as well as smaller fragments of the ECD. The Examiner acknowledges that the claimed derivatives of SEQ ID NO: 4 include functional derivatives, which can bind with IL-13, and non-functional derivatives, which are immunologically

interactive with antibodies to the NR4 receptor, or antibodies to functional derivatives of NR4.

With respect to "functional" derivatives of SEQ ID NO: 4, the Examiner contends that the specification provides little guidance regarding the positions in the protein that are tolerant to modifications without affecting the function of the protein. With respect to "non-functional" derivatives of SEQ ID NO: 4, the Examiner is of the opinion that the ability of a non-functional derivative to produce antibodies does not provide a use for such derivative. According to the Examiner, antibodies to a protein are only useful if the protein to which they bind has a use, and it would take undue experimentation to determine the derivatives that are associated with autoimmune diseases.

In an effort to favorably advance the prosecution, Applicants have amended Claims 1-2, 7-8, 38 and 47, and canceled Claims 9, 39-42 and 50-52. The present claims, as amended, further delineate "a haemopoietin receptor" as "an IL-13 receptor  $\alpha$ -chain", and further delineate the derivative of the IL-13 receptor  $\alpha$ -chain. More specifically, the derivative is presently characterized as an extracellular domain (ECD) of the IL-13 receptor  $\alpha$ -chain comprising amino acids 28-346 of SEQ ID No: 4 (i.e., the entire ECD of the human IL-13 receptor  $\alpha$ -chain), or comprising an amino acid sequence having at least 95% identity with amino acids 28-346 of SEQ ID No: 4. Further, the derivative is further characterized to bind with IL-13 or is immunologically interactive with antibodies to the IL-13 receptor  $\alpha$ -chain. Support for the amendment is found in specification, for example, on page 5, lines 12-17, Example 12 starting on page 40, and in Claims 39-43 as previously presented. No new matter is introduced by the amendment to the claims.

Applicants respectfully submit that the foregoing amendments have adequately addressed the Examiner's enablement rejection directed to the scope of the claims in respect to

"derivatives". Applicants respectfully submit that the derivative, as presently recited, is well defined. Based on the guidance provided in the specification, those skilled in the art would be able to obtain the derivative, as presently claimed, without undue experimentation.

Accordingly, the rejection of Claims 1, 2, 7-10, 25, 28-30, 36, 38-42 and 47-51 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling support, is overcome and withdrawal thereof is respectfully requested.

Claims 1, 2, 7-10, 25, 28-30, 36, 38-42 and 47-51 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner is concerned with the scope of the claims, particularly with respect to "derivatives."

Applicants respectfully submit that the derivative, as presently recited, is characterized in the claims both structurally and functionally. Specifically, the structure of the derivative is such that the derivative comprises amino acids 28-346 of SEQ ID No: 4 (i.e., the entire ECD of the human IL-13 receptor  $\alpha$ -chain), or comprises an amino acid sequence having at least 95% identity with amino acids 28-346 of SEQ ID No: 4. Further, the derivative is functionally characterized as binding with IL-13 or immunologically interactive with antibodies to the IL-13 receptor  $\alpha$ -chain. In light of the amendments to the claims, and the description in the specification regarding an ECD and derivatives thereof, Applicants respectfully submit that the claims, as presently recited and in relationship to a "derivative" of ECD, are adequately supported by the specification in a manner consistent with the written description requirement.

As such, the rejection of 1, 2, 7-10, 25, 28-30, 36, 38-42 and 47-51 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, is overcome and withdrawal thereof is respectfully requested.

Claims 38-42 and 48-51 are also rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement and containing new matter.

The Examiner alleges that the language in Claim 38, "a sequence of nucleotides which encodes an extracellular domain", is not limited to any particular portion of extracellular domain (ECD) and would encompass any ECD from any IL-13 receptor alpha chain. The Examiner maintains that the subject matter of claims 38-42 is not fully supported by the specification as originally filed.

Applicants respectfully submit that claim 38 has been amended to further define the structure and function of the extracellular domain. As discussed above, such amendment is fully supported by the specification and does not contain any new matter. Further, claims 39-42 have been canceled.

In addition, with respect to Claims 48-51, the Examiner objects to the recitation of specific nucleic acid fragments as constituting new matter.

Applicants have canceled claims 50-51 without prejudice. As to claim 48, it is observed that the Examiner acknowledges that the extracellular domain of the human NR4 protein consisting of (Thr28 to Thr346) is considered as supported by the specification, because these amino acid positions would "flow naturally" from the instant disclosure. The nucleic acid fragment of claim 48 represents the portion encoding the entire ECD (Thr28 to Thr346) of human IL-13 receptor alpha chain. Applicants further respectfully submit that the mature protein (Thr28 to Gln426) the human NR4 protein also naturally flows from the instant disclosure. See page 32, lines 25-26 (the description of Figure 7, identifying the mature protein of murine NR4) and Figure 7 (aligning the sequences of human and murine NR4). The nucleic acid fragment of claim 49 represents the portion encoding the mature form of human IL-13 receptor alpha chain.

Therefore, claims 48-49 are fully supported by the specification and do not contain new matter.

In view of the foregoing, the rejection of Claims 38-42 and 48-51 under 35 U.S.C. §112, first paragraph, as allegedly containing new matter, is overcome and withdrawal thereof is respectfully requested.

Applicants acknowledge that claims 43, 44, 46 and 52 are objected to as dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It is noted that claim 52 has been cancelled.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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